



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG - 4 2004

Mr. Harry Shippy
President
Nutritional Specialties, Inc.
1456 Katella Avenue
Anaheim, California 92805

Dear Mr. Shippy:

This is in response to your letter of June 23, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statement, among others, will be made for the product **Life Time Garli Dophilus Capsules**:

“[H]elp maintain...normal cholesterol levels....”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol levels that are already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to

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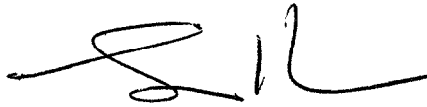
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regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

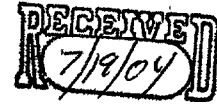
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



TUNG HAI™ Chlorella

June 23, 2004



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204

RE: Dietary Supplement Statement of Support Notification

To: Whom It May Concern:

Nutritional Specialties, Inc., 1456 E. Katella Ave. Anaheim, CA 92805, the distributor of the following dietary supplement products, intends to make the following statement of support: "Research indicates that your daily diet could benefit from adding a high quality garlic supplement designed to help maintain a healthy heart and circulation, normal cholesterol levels and a healthy natural defense system. The use of allicin for general well-being is on the increase, and its role as an antioxidant has also been, and continues to be, widely investigated. Allisure™ is the only supplement to provide the body with 100% yield of allicin. A patented extraction process produces allicin and locks all its goodness into convenient, on-a-day capsules designed for rapid absorption into your body. Garli Dophilus™ provides a 100% yield of Allisure™ stabilized allicin extract and a special strain of Lactobacillus Acidophilus helping to support the body's natural immune responses.."

This claim is being made for 100% Allisure™ Stabilized Allicin Extract, Lactobacillus Acidophilus

Which are contained in LifeTime® Garli Dophilus Capsules. This submission is being made in compliance with the requirements of 21 CFR 101.93.

The undersigned is an authorized representative of Nutritional Specialties, Inc. and certifies that the information contained in this notice is complete and accurate, and that Nutritional Specialties, Inc. has substantiation that the above statement is truthful and not misleading.

Harry G. Shippy
Signature
HARRY AUGUST SHIPPY
Full Name
PRESIDENT
Title

NUTRITIONAL SPECIALTIES, INC.

1456 E. Katella Avenue • Anaheim, CA 92805

1-800-333-6168 • 714-634-9340

Fax 714-634-9347

Email: lifetimevitamins@sbcglobal.net

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Life

**Garli Dophilus™
100% Allicin
With Acidophilus**

Supports the Body's Natural Defenses

Dietary Supplement

30 Capsules



Supplement Facts

Serving Size 1 Capsule
Servings Per Container :30

Amount Per Serving	% Daily Value
100% ALLISURE™ Stabilized Allicin Extract	180 mg. *
Lactobacillus Acidophilus	2 Billion *

*Daily Value not established.

Other Ingredients: Magnesium Stearate, Rice Powder, Gelatin and Water.

Suggested Use: As a food supplement, take 1 daily on an empty stomach.

Research indicates that your daily diet could benefit from adding a high quality garlic supplement designed to help maintain a healthy heart and circulation, normal cholesterol levels and a healthy natural defense system. The use of allicin for general well-being is on the increase, and its role as an antioxidant has also been, and continues to be, widely investigated.

Allisure™ is the only supplement to provide the body with 100% yield of allicin. A patented extraction process produces allicin and locks all its goodness into convenient, one-a-day capsules designed for rapid absorption into your body.

Garli Dophilus™ provides a 100% yield of ALLISURE™ stabilized allicin extract and a special strain of Lactobacillus Acidophilus helping to support the body's natural immune responses.

This statement has not been evaluated by the Food & Drug Administration (FDA).
This product is not intended to diagnose, cure or prevent any disease.

LifeTime® products are manufactured to meet strict quality control standards and formulated using only quality industry acceptable materials. An environmentally concerned company.

Formulated and Distributed by:
LifeTime®, Nutritional Specialists, Inc.
Anaheim, CA 92805
www.lifetimevitamins.com